

Cross-cultural adaptation and multi-centric validation of the Italian version of the Achilles tendon Total Rupture Score (ATRS)

Alberto Vascellari¹ · Pietro Spennacchio² · Alberto Combi³ · Alberto Grassi⁴ · Silvio Patella⁵ · Salvatore Bisicchia⁶ · Gian Luigi Canata⁷ · Stefano Zaffagnini⁴ · SIGASCOT Sport Committee

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Abstract

Purpose The purpose of this study was to translate the Achilles tendon Total Rupture Score (ATRS) into Italian and establish its cultural adaptiveness and validity.

Methods The original version of the ATRS was translated into Italian in accordance with the stages recommended by Guillemin. A web-based survey was developed to test the construct validity of the Italian ATRS. Eighty patients with an average age of 45.5 years (SD 11) were included in the study. The ATRS was completed twice at 5 days intervals for test–retest reliability. The intraclass correlation coefficient was used to calculate the test–retest reliability, and Cronbach’s α coefficient was used for internal consistency. Validity was evaluated by external correlation (Spearman’s rank correlation coefficient, r) of the ATRS with the Italian versions of the Victorian Institute of Sports Assessment–Achilles questionnaire (VISA-A), the 17-Italian Foot

Function Index (17-FFI), the Lower Extremity Functional Scale (LEFS), and the Short-Form 36 (SF-36).

Results The internal consistency ($\alpha = 0.97$) and the test–retest reliability (ICC = 0.96) were excellent. The correlation coefficient showed strong correlation of the Italian ATRS with the VISA-A and the LEFS ($r = 0.72$ and $r = 0.70$, respectively, $p < 0.0001$), a weak correlation with the 17-FFI ($r = -0.30$, $p = 0.007$), and high-to-moderate correlation with the physical functioning, bodily pain, physical role functioning, social functioning, role emotional, and vitality of the SF-36 ($r = 0.75$, $r = 0.61$, $r = 0.52$, $r = 0.49$, $r = 0.40$ and $r = 0.34$, respectively, $p < 0.0001$).

Conclusion The Italian version of the ATRS is a valid instrumentation to assess the functional limitations of Italian patients after Achilles tendon rupture.

Level of evidence III.

Keywords Achilles tendon rupture · ATRS · Cross-cultural · Validity · Reliability · Italian

✉ Alberto Vascellari
masvoz@gmail.com

¹ Orthopaedic and Traumatology Department, Oderzo Hospital, Oderzo, Treviso, Italy
² IRCCS Policlinico San Donato, San Donato, Milan, Italy
³ Orthopaedic and Traumatology Department, Fondazione I.R.C.C.S. Policlinico San Matteo, Pavia, Italy
⁴ 2nd Orthopaedic and Traumatology Clinic, Rizzoli Orthopaedic Institute, Bologna, Italy
⁵ Department of Orthopaedics and Traumatology, Bari University Hospital, Bari, Italy
⁶ Orthopaedic Surgery, San Pietro Fatebenefratelli Hospital, Rome, Italy
⁷ Centre of Sports Traumatology, Koelliker Hospital, Turin, Italy

Introduction

The Achilles tendon Total Rupture Score (ATRS) is the only patient-reported outcome measure (PROM) developed for specific outcome assessment of an Achilles tendon rupture [23]. Although several foot-specific questionnaires have been developed [4, 19, 24] and used for Achilles tendon ruptures, these systems were not specifically developed for Achilles tendon pathologies [17]. The ATRS has been shown to have good reliability, validity, and responsiveness for evaluating outcomes related to symptoms and physical activity in patients with an Achilles tendon rupture [6, 12, 18]. In order to use a questionnaire within

different language groups and in different cultural settings, the questionnaire must not only be translated into the new language, but also be adapted to the local culture. It must then be validated against the original version. The cross-cultural adaptation guidelines described by Guillemin are widely accepted and used for the translation and adaptation of questionnaires [3, 13]. Validated versions of ATRS have been currently published for use in English [6], Swedish [23], Danish [12], Turkish [16], and Persian [1]. To date, a validated Italian version of ATRS is not available. The cross-cultural adaptation of ATRS is needed prior to using in Italian-speaking countries. This ensures that the item equivalency between the original source and Italian versions is reached, and the content validity of the ATRS is maintained.

The aim of this study was to translate, cross-culturally adapt, and validate an Italian version of the ATRS questionnaire to provide a subjective method for the evaluation of the clinical condition after Achilles tendon rupture for Italian patients. A web-based survey was developed to test the construct validity of the Italian ATRS by determining the relationship between the Italian ATRS scores and the validated Italian versions of the Victorian Institute of Sports Assessment-Achilles questionnaire (VISA-A) [20], the 17-Italian Foot Function Index (17-FFI) [27], the Lower Extremity Functional Scale (LEFS) [5], and the Short-Form 36 (SF-36) [2]. There is compelling evidence that electronic and paper-and-pencil PROM deliver equivalent measures [8, 14, 25], and sometimes electronic ones are more reliable [9].

Materials and methods

The cross-cultural adaptation of the ATRS to Italian consisted of 6 steps, as described in Fig. 1.

Translation and cross-cultural adaptation process

Translation and cross-cultural adaptation of the ATRS were performed according to international guidelines [3, 13]. The original English version of the ATRS was independently translated into Italian by two non-medical professional translators (whose first language was Italian), and one physician. The new versions were analysed by a health care committee (a doctor, a nurse, and two physiotherapists) for Italian cultural characteristics, and an initial draft version was chosen. As recommended by Beaton et al. [3], a back-translation into English was then performed. Any inconsistency between the original English version and the retranslated English version was resolved in the second draft of the questionnaire. After the final questionnaire was approved (“Appendix 1: Italian version of the Achilles

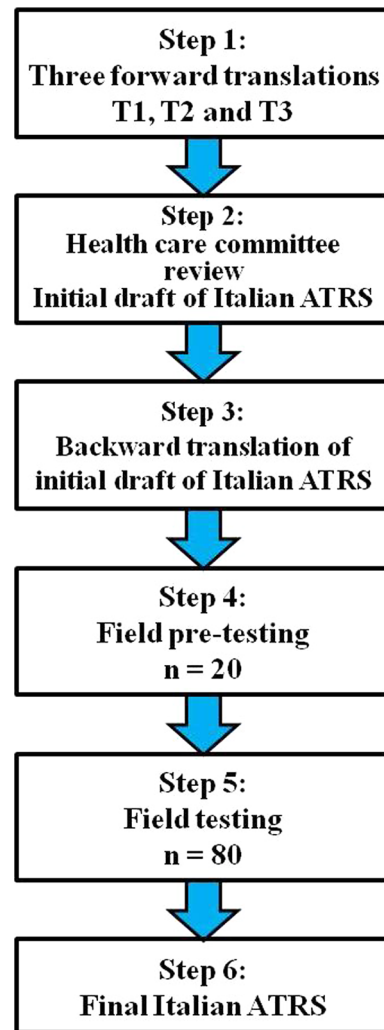


Fig. 1 Flow chart of the steps of cross-cultural adaptation of the Achilles tendon Total Rupture Score (ATRS) to Italian language

tendon Total Rupture Score (ATRS)”; the Italian version of the ATRS), it was pretested on 10 patients with foot or ankle pain and 10 patients without foot or ankle pain to ascertain that there were no problems with acceptance and comprehension of the questionnaire content. None of the patients reported difficulties to complete questionnaires because of language problems or redundancy.

Subjects and procedures for assessment of reliability and validity

The study was conducted as a questionnaire-based cross-sectional survey in a multi-centre independent population of patients with a previous Achilles tendon rupture treated in 7 centres affiliated to the Sport Committee of the Italian Society of Knee Arthroscopy Shoulder Cartilage Sport and Orthopaedic Technologies (SIGASCOT, Società

Italiana del Ginocchio Artroscopia Sport Cartilagine Tecnologie Ortopediche). An open-source platform (<https://drive.google.com>) was configured to collect the responses. The digital patient database of the Orthopaedic and Traumatology Department of each centre was retrospectively reviewed to identify all of the patients surgically treated for an acute Achilles tendon rupture. Patients younger than 18 and older than 80 were not included, nor were patients whose first language was not Italian. A total of 85 patients treated between January 2014 and June 2015 were enrolled in this study. Patients came from the Fondazione I.R.C.C.S. Policlinico San Matteo, Pavia ($n = 29$); the Treviso Regional Hospital and the Oderzo Hospital, Treviso ($n = 17$); the second Orthopaedic and Traumatology Clinic of Rizzoli Orthopaedic Institute, Bologna ($n = 15$); the Bari University Hospital ($n = 13$); the San Pietro Fatebenefratelli Hospital, Rome ($n = 8$); and the IRCCS Policlinico San Donato, Milan ($n = 2$). There is no agreed optimum method for determining an appropriate sample size to evaluate aspects of validity for patient-reported outcome measures. However, 50 patients have been advocated as the minimum requirement [18]. Therefore, it was deemed that our planned case series of 85 patients could provide sufficient power to investigate important aspects of validity for the ATRS. All patients gave their informed consent, upon receiving complete information on the study. According to Italian law, ethical approval for this study was not required because it involved only routine clinical follow-up. The patients were contacted by phone to present the research and to invite them to participate in the study and to fill in online the following self-reported outcome measures: the Italian version of the ATRS, the Italian versions of the VISA-A [20], the 17-FFI [27], the LEFS [5], and the SF-36 [2]. Moreover, all the English-speaking Italian patients ($n = 31$) were asked to complete both the English and the Italian versions of the ATRS to validate the scale. Comprehensibility and acceptance of the questionnaire were evaluated by the number of items completed and number of items left blank.

Validity

Evidence for construct validity must be accumulated by a priori hypothesized patterns of associations with other validated instruments to measure relatively similar constructs (for positive correlations) [11]. Spearman's rank correlation coefficient (r) was used to assess the association between the Italian ATRS and the Italian versions of the VISA-A, the 17-FFI, the LEFS, and different SF-36 subscales. It was hypothesized a priori that: (1) the correlations between the Italian ATRS and the subscales of Physical Health (PF, PR, BP) of the SF-36 would be high [12]; (2) the correlation between the Italian ATRS and VISA-A would be

high [12]; (3) the correlations between the Italian ATRS and the 17-FFI and the LEFS would be moderate to high; and (4) the correlations between the Italian ATRS and the SF-36 subscales of Physical Health (PF, PR, BP) would be higher than those between the Italian ATRS and the SF-36 subscales of Mental Health (GH, VT, SF, ER, MH). Spearman's coefficient was read as follows: strong correlation for values >0.50 ; moderate correlation for values between 0.35 and 0.50; weak correlation for values <0.35 [15]. The construct validity of the Italian ATRS questionnaire was defined as good if $\geq 75\%$ of the hypotheses were confirmed [26].

The ATRS consists of ten items evaluating aspects of symptoms and function. Each item ranges between 0 and 10 on a Likert scale. A maximal score of 100 indicates no symptoms and full function, whereas a minimum score of 0 indicates severe symptoms and no function [23].

The VISA-A is a PROM used to assess physical disability due to Achilles tendinopathy [20]. The VISA-A is based on an inverted numeric rating scale and results in a score range from 0 to 100 points with asymptomatic persons expected to score 100 points. A symptomatic person with severe Achilles tendinopathy would, on the other hand, be expected to score significantly lower.

The 17-FFI is a specific PROM of the impact of pathologies on foot and ankle function [27]. It consists of 17 items separated in three subscales: pain (5 items), disability (9 items), and limitation activity (3 items). The items are rated on an 11-point scale consisting of integers from 0 to 10. The poles are labelled "no pain" and "worst pain imaginable" (pain), "no difficulty" and "so difficult unable" (disability), and "none of the time" and "all of the time" (limitations). Scores are added and divided by the maximum total possible. Decimal points are eliminated by multiplying the score by 100.

The LEFS is a 20-item functional status questionnaire applicable to a wide spectrum of patients with lower extremity conditions of musculoskeletal origin [5]. The items investigate the degree of difficulty in performing different physical activities because of the problem in the lower extremity. Each item has four response options (0 = extreme difficulty or unable to perform activity; 4 = no difficulty). The scores for all the items are then used to calculate a scale score ranging from 0 (low functional level) to 80 (high functional level).

The SF-36 consists of 36 questions on the general health status of patients [2] with eight health concept subscales (physical function, role physical, bodily pain, general health, vitality, social function, role emotional, and mental health), which are then aggregated into two main scores. The physical and mental component summary scores represent weighted composite scores derived from the eight health concept scales. Each subscale score can vary from

0 to 100, with higher scores representing more desirable health states.

Reliability

Reliability, or test–retest reliability, was assessed by asking patients to complete another Italian ATRS 5 days after the first one, on another open-source platform (<https://drive.google.com>). It was assumed that the clinical situation did not change during this period. To minimize the risk of short-term clinical change, no treatment was provided during this period. All patients were told about the importance of completing the ATRS 5 days after the first one and were asked to refuse to do so if they had any doubt that they would be able to complete this instruction. The intraclass correlation coefficient r (ICC) (Two-way Random Effect Model Absolute Agreement Definition) was used to assess instrument test–retest reliability; reproducibility was considered to be “excellent” ($r > 0.75$), “good” ($0.75 < r < 0.40$), or “poor” ($r < 0.40$) [10].

Internal consistency

Internal consistency was tested using the Cronbach coefficient α [7], which summarizes the internal correlations of all items in a scale. The higher the coefficient (range 0–1), the more consistent is the scale and the greater the likelihood that it is tapping an underlying single variable on the questionnaire. Values equal or above 0.7 indicate acceptable reliability [26]. The coefficient was also calculated for elimination of 1 item in all 10 questions.

Statistical analysis

Descriptive statistics was used to report patients’ demographics as mean and standard deviation (SD). The Kolmogorov–Smirnov test was used to assess the assumption of normality.

A $p < 0.05$ was considered statistically significant. Data were entered into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond WA) and analysed using PSPP software (Free Software Foundation, Inc.) for Windows.

Results

The final Italian version of the ATRS is shown in “Appendix 1: Italian version of the Achilles tendon Total Rupture Score (ATRS)”. The forward- and back-translation of all of the items of the ATRS did not cause any major problems. Cross-cultural adaptation of the ATRS did not reveal any major problem, and no discrepancy was found.

Five patients (6.25 %) reported having no Internet connection available at home. A total of 80 patients completed the questionnaires. The demographic data of the cohort are listed in Table 1. There were no missing data for any ATRS item. Table 2 reports absolute values of all scores.

The Italian ATRS showed strong correlation with the VISA-A and the LEFS, a weak correlation with the 17-FFI, and high-to-moderate correlation with the physical functioning, bodily pain, physical role functioning, social functioning, role emotional, and vitality of the SF-36 (Table 3). Internal consistency was high (Cronbach’s α , 0.97). Elimination of one item in all 10 cases did not result in a value < 0.96 . All items correlated with the total score > 0.77 . A total of 18 patients filled in the questionnaire twice for testing of test–retest reliability. The intraclass correlation coefficient was $r = 0.96$, $p < 0.00001$. A total of 31 patients completed both the Italian and the English version of the ATRS, and a significant correlation was found ($r = 0.99$, $p < 0.00001$).

Discussion

The most important findings of the present study were that the proposed Italian version of the ATRS was reliable, valid, consistent, and comparable to the English version and that the Italian ATRS can be used in the Italian population to evaluate the clinical condition after Achilles tendon rupture. The translation and adaptation of the ATRS for an Italian context required no major cultural adaptation. The psychometric properties of the Italian ATRS were generally similar to the original ATRS. After adaptation, the Italian version of the ATRS seems to be a feasible instrument as

Table 1 Demographics of study cohorts

Variable	Validity study	Reliability study
Patients (n)	80	18
Gender		
Male	74	14
Female	6	4
Side		
Right	39	11
Left	41	7
Age (y)		
Mean (SD)	45.5 (11)	47.3 (10.4)
Range	25–79	27–71
Follow-up (m)		
Mean (SD)	11.0 (5.6)	10.1 (5.7)
Range	2–20	3–20

SD standard deviation

Table 2 Absolute values of all scores

Score	Mean (SD)	Maximum score
ATRS	68.5 (25.1)	100
VISA-A	68.6 (23.2)	100
17-FFI	36.9 (29.0)	0
LEFS	62.6 (17.0)	80
SF-36		
Physical functioning	82.3 (21.1)	100
Pain	81.2 (22.3)	100
Vitality	64.8 (16.4)	100
Role emotional	78.0 (36.9)	100
Role physical	75.9 (38.0)	100
Social functioning	78.9 (22.5)	100
Mental health	74.2 (15.6)	100
General health	72.8 (15.8)	100

SD standard deviation, ATRS Achilles tendon Total Rupture Score, VISA-A Victorian Institute of Sports Assessment-Achilles questionnaire, 17-FFI 17-Italian Foot Function Index, LEFS Lower Extremity Functional Scale, SF-36 Medical Outcome Study Short-Form 36 Health Survey

Table 3 Validity as measured by correlation between the ATRS and the VISA-A, the 17-FFI, the LEFS, and different SF-36 subscales

Score	Correlation with ATRS	<i>p</i>
VISA-A	0.72	<0.0001
17-FFI	−0.30	0.007
LEFS	0.70	<0.0001
SF-36		
Physical functioning	0.75	<0.0001
Pain	0.61	<0.0001
Vitality	0.34	0.0023
Role emotional	0.40	0.0002
Role physical	0.52	<0.0001
Social functioning	0.49	<0.0001
Mental health	0.20	n.s.
General health	0.18	n.s.

ATRS Achilles tendon Total Rupture Score, VISA-A Victorian Institute of Sports Assessment-Achilles questionnaire, 17-FFI 17-Italian Foot Function Index, LEFS Lower Extremity Functional Scale, SF-36 Medical Outcome Study Short-Form 36 Health Survey

illustrated by the absence of missing data that reflects the good acceptance of the Italian ATRS.

The construct validity of the ATRS questionnaire was determined by comparing the ATRS with selected outcome measures (the subscales of the SF-36 [2] the VISA-A [20], the 17-FFI [27] and the LEFS [5]). The Italian versions of the four questionnaires have been validated [2, 5, 20, 27], but to our knowledge, there is no cross-culturally validated Italian version of the ATRS score. As it was reported in

the literature [26], it is not recommended to try to justify specific low correlations; on the contrary, it is more appropriate to use predefined hypotheses in order to verify the validity of a construct. Despite some low correlations, all of the a priori hypotheses were mainly confirmed in our sample. This finding is supported by the satisfactory correlations between the Italian ATRS and the VISA-A, as well as by the higher correlations between the SF-36 subscales assessing related constructs (convergent validity) and the lower correlations between the subscales measuring different constructs (divergent validity). Our findings are in line with most cross-national adaptations, with higher correlations between the ATRS and SF-36 subscales of Physical Health [12, 16, 23]. A correlation of $r = 0.72$ with the VISA-A questionnaire is relevant because the instrument measures pain, symptoms, and physical activity aspects among patients with chronic Achilles tendinopathy [20, 23]. The VISA-A questionnaire also contains questions that were considered to have low face validity for patients with Achilles tendon total rupture.

In this validation study, Cronbach's alpha coefficient was above 0.70. This indicates a good internal consistency, which is in line with those of the original developers [23] and most cross-national adaptations [1, 12, 16, 18]. Cronbach's α when each item was deleted did not rise or fall, confirming that all items are related and should be retained in the overall test.

The test–retest indicated excellent reliability, in accordance with the Swedish, English, Danish, Persian, and Turkish versions of the ATRS [1, 12, 16, 23]. We retested the patients after 5 days, which is within the recommended time frame ranging from 2 days to 2 weeks [21]. The 5 days interval was chosen because it is unlikely that the patients remember the content of the questionnaire, and no change in disease state is expected.

The major limitation of this study is that responsiveness, which has been defined as the ability of a questionnaire to detect change over time in the construct to be measured [22], was not evaluated. Responsiveness is considered an important measurement property of a PROM used for treatment evaluation and needs to be evaluated for the Italian version in future research. Furthermore, the patients enrolled in the study were at different stages of rehabilitation, in an interval from 2 to 20 months after their injury. The small sample size of patients enrolled in the reliability study state of rehabilitation could have influence the reliability data, because those who were in the early rehabilitation phase could have experienced a change in condition between the 2 tests. However, the test–retest indicated excellent reliability in accordance with previous versions of the ATRS [12, 16, 23]. Questions 8 and 9 in the ATRS questionnaire require that patients can run and jump, and jumping and running are not possible after 2 months. Thus,

the ATRS questionnaire contains questions that are not well adapted to all stages of rehabilitation. Nevertheless, patients evaluated 2 months after their injury completed all 10 items even if were able to submit the Web form or possibly skip to the next questionnaire if some of the questions were not answered, and there were no missing data for any ATRS item.

Strength of this study is that the current sample is highly representative of the general Italian population. In fact, it refers to areas in different regions across Italy.

The clinical relevance of this study is that the proposed Italian version of the ATRS was reliable, valid, consistent, and comparable to the English version. The use of the cross-culturally adapted Italian ATRS may be considered to evaluate the clinical condition after Achilles tendon rupture in day-by-day clinical practice and research in the Italian population.

Appendix 1: Italian version of the Achilles tendon Total Rupture Score (ATRS)

Data: ___ / ___ / _____ Data di nascita ___ / ___ / _____

Nome e Cognome: _____

ISTRUZIONI: Questo questionario intende valutare le limitazioni/difficoltà che Lei prova a causa della lesione del Suo tendine di Achille.

Risponda a ciascuna domanda, quantificando le Sue limitazioni/difficoltà da 0 a 10 (solo una risposta per ciascuna domanda). Ricordi: 0=grave limitazione, 10=nessuna limitazione. Marchi il numero che meglio rispecchia il Suo livello di impedimento.

1. Ha delle limitazioni dovute alla diminuzione della forza del polpaccio/tendine di achille/piede?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

2. Ha delle limitazioni dovute alla stanchezza al polpaccio/tendine di achille/piede?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

3. Ha delle limitazioni dovute alla rigidità del polpaccio/tendine di achille/piede?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

4. Ha delle limitazioni dovute al dolore al polpaccio/tendine di achille/piede?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

5. Ha difficoltà nello svolgimento delle Sue attività quotidiane abituali?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

Conclusion

In conclusion, the Italian version of the ATRS proved equivalent evaluation capacities to the original version, which makes it a valid instrumentation to assess the functional limitations of patients after Achilles tendon rupture.

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Compliance with ethical standards

Conflict of interest All the authors declare that they have no conflict of interest related to the topic of this article.

6. Ha difficoltà quando cammina su una superficie irregolare?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

7. Ha difficoltà quando sale rapidamente le scale o cammina in salita?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

8. Ha difficoltà durante le attività che includono la corsa?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

9. Ha difficoltà durante le attività che includono i salti?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

10. E' limitato quando esegue lavori pesanti?

0 1 2 3 4 5 6 7 8 9 10 (nessuna limitazione)

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